MAR 2 2 2005

K050630

Summary of Safety and Effectiveness

Prepared 8 March 2005

General Provisions

Submitter of 510(k) Premarket Notification:	Boston Scientific - Precision Vascular 2405 West Orton Circle West Valley City, UT 84119 Phone: 801.974.1700 Fax: 801.974.1740
Contact Person:	Rick Gaykowski Vice President, Regulatory/Clinical Affairs & Quality Systems
Device Trade Name:	***"Pivot™" Steerable*** Microcatheter
Device Generic Name:	Infusion Catheter

Predicate Devices

The predicate devices are listed below.

Device	Manufacturer	510(k) Number/Date	Pro Code
SDS 0.018"	PVS, Inc.	K020733, 21 March 2002	KRA
SDS 0.010"	PVS, Inc.	K032494, 05 Sep 2003	KRA
Pivot "SDS"	PVS, Inc.	K033726, 16 Jan 2004	KRA

Classification

Class II, 21 CFR 870.1210, Continuous Flush Catheter, KRA

Performance Standards

Performance standards have not been established by FDA under section 514 of the Federal Food, Drug and Cosmetic Act.

Intended Use

The ***"Pivot™" Steerable*** Microcatheter is intended to be used to access tortuous vasculature for sub-selective controlled infusion or delivery of diagnostic, embolic, and therapeutic agents into the distal, peripheral, coronary, and neurovasculature, and for guide wire exchange/support during diagnostic or interventional procedures.

Device Description

The ***"Pivot™" Steerable*** Microcatheter is a 1.9F/2.4F (nominal distal/proximal) tubular device, ~150 cm in length, with a lumen to be used for delivery of contrast, drugs, or embolics. The lumen is constructed from a polymeric material and has an inside diameter of 0.017". The device is coated on the outer diameter with a lubricious coating over the distal segment of the device. Two radiopaque markers are positioned at the distal tip of the device to aid visualization under fluoroscopy. The proximal end of the device has a standard luer adapter for attachment of accessories and can be used to flush the lumen. The subject device has the ability to access distal, tortuous vasculature over a guide wire, deliver embolics and agents, and has the ability to be steered like a guide wire as needed.

Technological Characteristics	Technological similarities between the "***Pivot***™" ***Steerable*** Microcatheter and predicate devices include the basal tubular design and dimensions, polymeric materials and construction, and hydrophilic coating. In instances where the technological characteristics may differ slightly, it has been demonstrated that there are no new questions raised regarding safety and efficacy of the "***Pivot***™" ***Steerable*** Microcatheter.
Safety and Performance Tests	Biocompatibility of the "***Pivot***™" ***Steerable*** Microcatheter has been verified in accordance with ISO 10993-1, Biocompatibility of Medical Devices – Part 1. Test results confirmed biocompatibility of the subject device when tested as an external communicating, blood contact, short duration (<24 hours) devices. Performance testing of the "***Pivot***™" ***Steerable*** Microcatheter was conducted in accordance with ISO 10555-1, Sterile, Single-Use Intravascular Catheters – Part 1. Verification testing for the subject device included dimensional inspection, hub integrity, flow rate measurements, burst strength, tensile strength, guidewire compatibility testing and performance under simulated conditions. Subject product testing has yielded acceptable results. In addition, torsional strength, torqueability, and corrosion resistance tests have also yielded acceptable results. The results of these tests, in conjunction with the substantial equivalence claims as outlined in the premarket notification, effectively demonstrate the "***Pivot***™" ***Steerable*** Microcatheter is substantial equivalent to the cited predicate devices.
Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, and safety and performance testing, the subject "***Pivot***™" ***Steerable*** Microcatheter meets the minimum requirements that are considered adequate for its intended use and is substantially equivalent in design, materials, sterilization, principles of operation and indications for use to current commercially available catheters/cited predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 2 2005

Mr. Rick Gaykowski
Vice President, Regulatory/Clinical Affairs & Quality Systems
Boston Scientific – Precision Vascular
2405 West Orton Circle
West Valley City, UT 84119

Re: K050630
Trade/Device Name: *Pivot*™ Steerable Microcatheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous flush catheter
Regulatory Class: II
Product Code: KRA
Dated: March 10, 2005
Received: March 11, 2005

Dear Mr. Gaykowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Lechner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K050630

Device Name: "***Pivot***™" ***Steerable*** Microcatheter

Indications for Use:

The "***Pivot***™" ***Steerable*** Microcatheter is intended to be used to access tortuous vasculature for sub-selective controlled infusion or delivery of diagnostic, embolic, and therapeutic agents into the distal, peripheral, coronary, and neurovasculature, and for guidewire exchange/support during diagnostic or interventional procedures.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____

(Per 21 CFR 801.109)

Donna P. Lichtenfeld

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K050630